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Docket No.: 300.1003  
Date: January 13, 2005

In re application of: Chih-Ming CHEN, et al.  
Serial No.: 09/435,576  
Filed: November 8, 1999  
For: **HMG-COA REDUCTASE INHIBITOR EXTENDED RELEASE FORMULATION**

Sir:

Transmitted herewith is a **Statement of Substance of Interview under 37 CFR §1.133** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.
- ☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:
  
- ☐ Also transmitted herewith are:
  - ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
  - ☐ Other:
  
- ☐ Check(s) in the amount of **\$ .00** is/are attached to cover:
  - ☐ Filing fee for additional claims under 37 C.F.R. 1.16
  - ☐ Petition fee for extension under 37 C.F.R. 1.136
  - ☐ Other:
  
- ☒ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
  - ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
  - ☒ Any patent application processing fees under 37 C.F.R. 1.17.
  - ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with sufficient postage to the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on

January 13, 2005  
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BY: 



300.1003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: Sharmila S. Gollamudi Art Unit: 1616

Re: Application of: Chih-Ming CHEN, et al.

Serial No.: 09/435,576

Filed: November 8, 1999

For: **HMG-COA REDUCTASE INHIBITOR  
EXTENDED RELEASE FORMULATION**

**STATEMENT OF SUBSTANCE  
OF INTERVIEW UNDER 37 CFR §1.133**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

January 13, 2005

Sir:

The undersigned gratefully acknowledges the courtesies extended by Examiner Gollamudi and Examiner Kunz during the personal interview of December 14, 2004 wherein all of the pending claims were discussed. This Statement of Substance of Interview is in response to the Examiner's Interview Summary mailed December 16, 2004.

During the interview, the issues regarding (i) the Cheng reference, and (ii) the Examiner's assertion that functional limitations are equivalent to intended use were discussed.

**(i) Are Functional Limitations Equivalent To Intended Use**

During the interview, it was discussed that the Tmax limitation of the claims is a property of the formulation regardless of what use the formulation is used for. It was discussed that an example of an intended use would be the use of a formulation to treat a specific disease state.

e.g., cancer. However, regardless of the reason the presently claimed formulation is administered (i.e., intended use), the Tmax will always occur at the same specific time range after administration. It was further discussed that an intended use (i.e., treatment of a disease state) may or may not be met, in contrast to the Tmax limitation which is always a property of the formulation (and a limitation of the claimed invention).

The Examiner was respectfully reminded that “[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a *particular capability* or purpose that is served by the recited element, ingredient or step.” (Emphasis added) MPEP 2173.05(g).

During the interview, it was pointed out that the Tmax is a functional limitation and in view of the above discussion, the Examiner agreed that the Tmax limitation is not an intended use.

#### (ii) The Cheng Reference

During the interview, the undersigned pointed out that it is incorrect for the Office to rely on the Cheng reference as a basis for the Examiner’s position that the prior art provides “guidance” for the claimed Tmax ranges. The Examiner’s position on this issue is set forth in the previous Office Action (“Cheng et al state that ‘the dog may not be a good model for predicting relative bioavailability of lovastatin or simvastatin.’ This is by no means is [*sic*] a conclusive statement that the dog data is not instructive with respect to humans”).

It was pointed out that the Tmax reported in Cheng et al. for the sustained and controlled-release formulations after administration to dogs ranged from of  $1.8 \pm 0.4$  to  $7.5 \pm 1.2$ . It was then discussed that the point regarding whether dog data is instructive with respect to

humans is irrelevant. If dog data is instructive with respect to humans, Cheng does not teach or suggest the claimed Tmax ranges in humans in view of the above data. Alternatively, if dog data is not instructive with respect to humans, Cheng still does not teach or suggest the claimed Tmax in humans of about 10 to about 32 hours based on the above data.

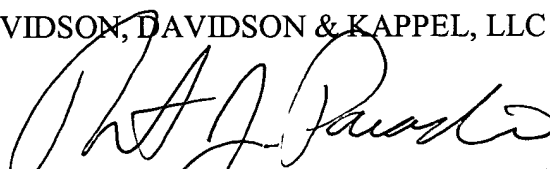
During the interview, it was also pointed out to the Examiner that the Tmax reported in Cheng et al. for the sustained and controlled-release formulations after administration to humans was  $4.2 \pm 0.7$  and  $4.7 \pm 1.0$ .

The Examiner agreed with Applicant's positions with respect to the dog data and human data and the Interview Summary included the statement that "[t]he references cited in the Office Action seem to be lacking motivation to manipulate the Tmax from 6.7 to 10 hours."

The Examiner is requested to telephone the undersigned in the event a further discussion will advance the prosecution of this application.

Respectfully submitted,

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